Remarks

The Office Action mailed October 10, 2006 has been received and reviewed. Claims 1, 17, 40, 50, 57, and 76-77 having been amended, claims 71-75 having been cancelled without prejudice, the pending claims are claims 1-70 and 76-77. Reconsideration and withdrawal of the rejections are respectfully requested.

Each of the independent claims has been amended to recite "a segmented polymer" comprising "a soft segment" . . . "with the proviso that the polymer is substantially free of carbonate linkages." These amendments are supported, for example, on page 7, lines 22-25, page 11, lines 1-3, and page 17, lines 4-7, of the present specification.

Double Patenting Rejection

Claims 1-70 and 76 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-29 of U.S. Patent No. 6,984,700. Claims 1-70 and 76 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-28, 30-34, and 39-40 of copending Application No. 10/663,925. Claims 1-70 and 76 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 24-46 and 48 of copending Application No. 11/133,627. Upon an indication of otherwise allowable subject matter and in the event these rejections are maintained, Applicants will provide an appropriate response.

The 35 U.S.C. §112, First Paragraph, Rejection

The Examiner rejected claims 15, 34, and 55 under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Specifically, the Examiner alleged that the "[a]pplicants have failed to define the term, 'substantially free', as it pertains to ether, ester, and carbonate linkages. It cannot be determined what quantity of these linkages the language

provides for. The issue is further aggravated by the fact that applicants specifically recite at page 16 of the specification that polymers containing these linkages may be produced" (e.g., pages 2-3, Non-Final Office Action mailed 10 October 2006). Applicants respectfully traverse the rejection.

The proper standard to consider in making the present rejection is: "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed." (*In re Gosteli,* 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618, (Fed. Cir. 1989). Applicants respectfully submit that one skilled in the art, considering the entire specification, would clearly recognize the Applicants were in possession of the invention as claimed. Applicants respectfully submit that the Examiner has taken too narrow a view of the specification in making the rejection, and that one skilled in the art considering the entire specification would recognize that Applicants did, in fact, possess a polymer that is "substantially free" of ether, ester, and carbonate linkages as recited in the claims.

Even though Applicants have stated that polymers containing these linkages may be produced, Applicants have also stated that polymers without these linkages are preferred. See, for example, Applicants' specification at page 4, lines 1-2, page 11, lines 1-3, and page 17, lines 4-7.

To sustain this rejection the Examiner has the burden of presenting evidence or reasons why persons skilled in the art would not recognize in an applicants' disclosure a description of the invention defined by the claims. *In re Wertheim* 541 F.2d 257, 265, 191 USPQ 90, 98 (CCPA 1976). Such evidence or reasoning is required for a proper rejection under Section 112, first paragraph. *See, e.g.,* M.P.E.P. §2163.04. Failure to provide such evidence or reasoning makes it impossible for Applicants to completely and properly address the basis for this rejection.

In summary, the proper standard for a "written description" rejection is whether or not the specification indicates to one of ordinary skill in the art that the Applicants had possession of the invention as claimed. At a minimum, page 4, lines 1-2, page 11, lines 1-3, and page 17, lines 4-7 of the present specification would indicate that one of ordinary skill in the art would

recognize that Applicants did, in fact, possess the claimed invention at the time of filing. Applicants respectfully submit that claims 15, 34, and 55 do satisfy the requirements of §112, first paragraph. Reconsideration and withdrawal of this rejection are, therefore, respectfully requested.

The Examiner also rejected claims 1-12, 14-16, and 40-56 under 35 U.S.C. §112, first paragraph, as containing subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Specifically, the Examiner alleged that "the specification, while being enabling for polymers produced from the reaction of hydroxyl or amine functional compounds containing quaternary carbons and silicon groups, does not reasonably provide enablement for polymers produced by reacting other than hydroxyl or amine functional compounds containing quaternary carbons and silicon groups" (e.g., page 3, Non-Final Office Action mailed 10 October 2006). Applicants respectfully traverse the rejection.

"A specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, unless there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support." M.P.E.P. §2164.04. "As long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement of 35 U.S.C. 112 is satisfied." M.P.E.P. §2164.01(b).

Applicants respectfully submit that one reasonably skilled in the art, in view of the present specification, could make or use the entire scope of the claimed invention. Specifically, claims 1, 40, and 50 each recite a "group of the formula: $-[-(R^1)-(-Z-(R^2)_m-)_p-(-Si(R)_2-V_r-)_s-]_q-$ wherein . . . ." The specification also recites that:

> Polymers of the present invention can be linear, branched, or crosslinked. This can be done using polyfunctional isocyanates or polyols (e.g., diols, triols, etc.) or using compounds having ***unsaturation*** or other functional groups (e.g., ***thiols***) in one or more monomers with radiation crosslinking, for example. Such methods are well known to those of skill in the art.

(e.g., page 11, lines 15-20, emphasis added). Thus, Applicants submit that one of skill in the art would recognize other Y groups may be substituted for OH or NH_2.

Finally, the Examiner has not alleged any reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support.

For at least the reasons presented herein above, Applicants respectfully submit that the specification adequately enables the entire scope of independent claims 1, 40, and 50. Reconsideration and withdrawal of the rejection are respectfully requested.

The 35 U.S.C. §112, Second Paragraph, Rejection

The Examiner rejected claims 15, 34, and 55 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter, which Applicants regard as the invention. Specifically, the Examiner alleged that "in the absence of a definition of 'substantially free', it cannot be determined what quantity of the ether, ester, and carbonate linkages may be present and still satisfy the claims" (e.g., page 3, Non-Final Office Action mailed 10 October 2006). Applicants respectfully traverse the rejection.

Applicants submit that the claim is clear and, when read in view of the specification, particularly points out and conveys Applicants' invention to one of skill in the art. For example, the specification recites that "[p]olymers of the present invention may be random, alternating, block, star block, segmented, or combinations thereof. Preferably, the polymer is a segmented polyurethane. Such polymers are preferably used as biomaterials in medical devices. Preferred polymers are also preferably substantially free of ester, ether, and carbonate linkages"(e.g., page 3, line 29 to page 4, line 2). The specification also recites that "both the hard and soft segments are themselves substantially ether-free, ester-free, and carbonate-free polyurethanes, polyureas, or combinations thereof" (e.g., page 11, lines 1-3). Furthermore, it is stated in the specification

at page 17, lines 4-7, that polyester, polyether, and polycarbonate polyols "are less preferred because they produce less biostable materials."

Further, the term "substantially" has been held to be definite in various contexts when those of ordinary skill in the art understand what is claimed in light of the specification. *See* M.P.E.P. § 2173.05(b). For example, the Federal Circuit held that the limitation "which produces substantially equal E and H plane illumination patterns" was definite because one of ordinary skill in the art would know what was meant by "substantially equal." *Andrew Corp. v. Gabriel Electronics,* 6 U.S.P.Q.2d 2010 (Fed. Cir. 1988).

Here, those skilled in the art would understand that the term "substantially free of ester, ether, and carbonate linkages" refers to an amount of such linkages that produces biostable materials. Problems with the lack of biostability in the medical device arena are described in the Background of the Invention at pages 1-3 of Applicants' specification. When read in this context, one of skill in the art would understand that this would include materials that are totally free of such linkages, as well as materials with a minor amount of such linkages, as long as the materials are sufficiently biostable so as to not cause failure of a medical device.

Thus, Applicants respectfully submit that in view of the present specification, one of skill in the art would recognize and understand the term "substantially free" and that the present claims clearly and distinctly convey Applicants' invention.

In view of the remarks presented herein, Applicants respectfully request that the Examiner reconsider and withdraw the rejection under 35 U.S.C. §112, second paragraph.

The 35 U.S.C. §102 Rejections

The Examiner rejected claims 1-11, 14-16, and 40-49 under 35 U.S.C. §102(b) as being anticipated by Deichert et al. (U.S. Patent No. 4,208,506). Independent claims 1 and 40 have been amended; however, to the extent that the rejection applies to current claims 1-11, 14-16, and 40-49, Applicants respectfully traverse the rejection.

"[F]or anticipation under 35 U.S.C. §102, the reference must teach *every aspect* of the claimed invention either explicitly or impliedly." M.P.E.P. §706.02 (emphasis added).

Applicants respectfully submit that claims 1-11, 14-16, and 40-49 are not anticipated by Deichert et al. because such document does not teach each and every aspect of the claimed invention. For example, Deichert et al. disclose "[m]onomeric polyparaffinsiloxanes end-capped with activated unsaturated groups and polymers and copolymers thereof . . . for use as contact lenses and biomedical devices with improved properties" (e.g., abstract). However, Deichert et al. do not disclose a "***segmented*** polymer comprising a ***soft segment*** comprising a group of the formula: $-[-(R^1)_n-(-Z-(R^2)_m-)_p-(-Si(R)_2-V_r-)_s-]_q-$ wherein . . ." (e.g., independent claims 1 and 40, emphasis added).

As such, Applicants respectfully submit that claims 1-11, 14-16, and 40-49 are not anticipated by Deichert et al. Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §102(b).

The Examiner also rejected claims 1-2, 4, 6-16, 40-41, 43, 45-51, and 53-56 under 35 U.S.C. §102(e) as being anticipated by Kato et al. (U.S. Patent No. 6,867,325). Independent claims 1, 40, and 50 have been amended; however, to the extent that the rejection applies to current claims 1-2, 4, 6-16, 40-41, 43, 45-51, and 53-56, Applicants respectfully traverse the rejection.

Applicants respectfully submit that claims 1-2, 4, 6-16, 40-41, 43, 45-51, and 53-56 are not anticipated by Kato et al. because such document does not teach each and every aspect of the claimed invention. For example, Kato et al. disclose an "organosiloxane polymer comprising recurring units of the general formula (1) and having a weight average molecular weight of 1,000-500,000" (e.g., abstract). However, Kato et al. do not disclose a ***segmented*** "polymer comprising a ***soft segment*** comprising a group of the formula: $-[-(R^1)_n-(-Z-(R^2)_m-)_p-(-Si(R)_2-V_r-)_s-]_q-$ wherein . . ." (e.g., independent claims 1, 40, and 50, emphasis added).

As such, Applicants respectfully submit that claims 1-2, 4, 6-16, 40-41, 43, 45-51, and 53-56 are not anticipated by Kato et al. Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §102(e).

The 35 U.S.C. §103(a) Rejections

The Examiner rejected claims 1-70 and 76 under 35 U.S.C. §103(a) as being unpatentable over Meijs et al. (U.S. Patent No. 6,313,254) or WO 01/07499 or WO 00/64971 or WO 99/50327 or WO 98/54242 or WO 99/03863, each in view of Pinchuk '240 (U.S. Patent No. 6,197,240) or Benz et al. (U.S. Patent Application Publication No. 2003/0125499) or Pinchuk '973 (European Patent Application Publication No. EP 821973). Independent claims 1, 17, 40, 50, 57, and 76 have been amended; however, to the extent that the rejection applies to current claims 1-70 and 76, Applicants respectfully traverse the rejection.

"To establish a *prima facie* case of obviousness . . . there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings" M.P.E.P. §2143.

Applicants respectfully submit that there is no suggestion or motivation, either in the documents or in the knowledge generally available to one of ordinary skill in the art, to modify the documents. For example, Applicants submit that the documents used as primary references (e.g., U.S. Patent No. 6,313,254, and PCT Patent Application Publication Nos. WO 01/07499, 00/64971, 99/50327, 98/54242, and 99/03863) disclose various silicon-containing polymers, which are prepared by condensation polymerization techniques. The Examiner alleged that the "primary references fail to teach a specific preference for the incorporation of these quaternary carbon-containing groups within the silicon group-containing polyol or polyamine" (e.g., page 7, Non-Final Office Action mailed 10 October 2006).

In these documents used as primary references, there are no specific examples of segmented polymers that are substantially free of carbonate linkages, wherein the soft segments include a group of the recited formula, in particular a quaternary carbon-containing group (one carbon with 4 other carbons attached), and no specific preference for the incorporation of these quaternary carbon-containing groups, as suggested by the Examiner (although there are lists of species containing quaternary carbon-containing groups in certain of these documents). Furthermore, there is no enabling teaching, suggestion, or recognition of the advantages of the

specific groups forming the soft segments of segmented polymers as recited in Applicants' claims.

Although Pinchuk '240 and Pinchuk '973 theoretically disclose that the "most inert polymers are those with the most 'quaternary' carbons" (e.g., col. 3, l. 62-64), the polyolefinic copolymer elastomers ***do not contain silicon***, and are made by anionic or carbocationic polymerization (see, e.g., col. 7, l. 9-11). Applicants submit that one of skill in the art would have no motivation to combine the silicon-containing polymers of the documents used as primary references with the non-silicon-containing polyolefinic copolymer elastomers of Pinchuk '240 and Pinchuk '973.

With regard to Benz et al. (U.S. Patent Application Publication No. 2003/0125499), "[e]ffective November 29, 1999, subject matter which was prior art under former 35 U.S.C. 103 via 35 U.S.C. 102(e) is now disqualified as prior art against the claimed invention if that subject matter and the claimed invention 'were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person'" (e.g., M.P.E.P. §706.02(l)(1)).

Applicants respectfully submit that Benz et al. (U.S. Patent Application Publication No. 2003/0125499) is not available as prior art for purposes of obviousness in view of 35 U.S.C. §103(c) as effective November 29, 1999. At the time the invention of the instant application was made, the claimed invention and Benz et al. (U.S. Patent Application Publication No. 2003/0125499), were owned by or subject to an obligation of assignment to the same entity.

As such, Applicants respectfully submit that claims 1-70 and 76 are not obvious over Meijs et al. (U.S. Patent No. 6,313,254) or WO 01/07499 or WO 00/64971 or WO 99/50327 or WO 98/54242 or WO 99/03863, each in view of Pinchuk '240 (U.S. Patent No. 6,197,240) or Benz et al. (U.S. Patent Application Publication No. 2003/0125499) or Pinchuk '973 (European Patent Application Publication No. EP 821973). Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §103(a).

The Examiner also rejected claims 1-16 and 40-56 under 35 U.S.C. §103(a) as being unpatentable over Meijs et al. (U.S. Patent No. 6,313,254) or WO 01/07499 or WO 00/64971 or WO 99/50327 or WO 98/54242 or WO 99/03863, each in view of Pinchuk (U.S. Patent No. 6,197,240) or Benz et al. (U.S. Patent Application Publication No. 2003/0125499) or Pinchuk (European Patent Application Publication No. EP 821973), and further in view of Kennedy (U.S. Patent No. 4,316,973). Independent claims 1, 40, and 50 have been amended. However, to the extent that the rejection applies to claims 1-16 and 40-56, Applicants respectfully traverse the rejection.

Applicants respectfully submit that there is no suggestion or motivation, either in the documents or in the knowledge generally available to one of ordinary skill in the art, to modify the documents. The deficiencies of Meijs et al. (U.S. Patent No. 6,313,254) or WO 01/07499 or WO 00/64971 or WO 99/50327 or WO 98/54242 or WO 99/03863, each in view of Pinchuk '240 (U.S. Patent No. 6,197,240) or Benz et al. (U.S. Patent Application Publication No. 2003/0125499) or Pinchuk '973 (European Patent Application Publication No. EP 821973) have been discussed herein above. Applicants respectfully submit that Kennedy does not supply subject matter that would correct the deficiencies of Meijs et al. (U.S. Patent No. 6,313,254) or WO 01/07499 or WO 00/64971 or WO 99/50327 or WO 98/54242 or WO 99/03863, each in view of Pinchuk '240 (U.S. Patent No. 6,197,240) or Benz et al. (U.S. Patent Application Publication No. 2003/0125499) or Pinchuk '973 (European Patent Application Publication No. EP 821973) noted herein above.

As such, Applicants respectfully submit that claims 1-16 and 40-56 are not obvious over Meijs et al. (U.S. Patent No. 6,313,254) or WO 01/07499 or WO 00/64971 or WO 99/50327 or WO 98/54242 or WO 99/03863, each in view of Pinchuk '240 (U.S. Patent No. 6,197,240) or Benz et al. (U.S. Patent Application Publication No. 2003/0125499) or Pinchuk '973 (European Patent Application Publication No. EP 821973), and further in view of Kennedy (U.S. Patent No. 4,316,973). Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §103(a).

Summary

It is respectfully submitted that all the pending claims are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

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